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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/672,020	09/29/2000	Thomas J. Gardella	0609.4820002/SRL/TBB	2982

26111 7590 10/13/2004

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EXAMINER

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 10/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/672,020

**Applicant(s)**

GARDELLA ET AL.

**Examiner**

Joseph F Murphy

**Art Unit**

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-8 and 10-44 is/are pending in the application.
- 4a) Of the above claim(s) 4-7 and 13-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8, 42, 44 is/are rejected.
- 7) ☒ Claim(s) 1,10-12 and 43 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Formal Matters***

Claims 1, 3-8, 10-44 are pending. Claims 1, 8, 10-12, 42-44 are under consideration. Claims 4-7, 13-41 stand withdrawn from consideration pursuant to 37 CFR 1.142(b).

### ***Response to Amendment***

The rejection of claims 1, 8, 10-12, 42 under 35 U.S.C. 112, first paragraph, has been obviated by Applicant's amendment and are thus withdrawn.

The rejection of claims 1, 10-12, 42 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

New and remaining issues are set forth below.

### ***Claim Objections***

Claims 1, 8, 10-12, 42-44 are objected to because of the following informalities: The use of the subscript number identifiers of the X amino acids are objected to because they make the claims unclear. For instance, claims 42, 44 refer to fragments containing amino acids 1-9 etc., while SEQ ID NO: 1 is listed as containing X<sub>01</sub> etc., this is confusing since it is not clear whether the 1 is the same as the 01. This claim could be clarified by using letters as the subscript identifiers for the X amino acids, e.g. X<sub>a</sub>. Appropriate correction is required.

***Claim Rejections - 35 USC § 112 second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 42 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation "The biologically active polypeptide of claim 1". There is insufficient antecedent basis for this limitation in the claim, because the base claim has been amendment to remove the language "biological activity".

Claims 8 stands rejected as being vague and indefinite in the recitation of the term "biologically active". The term "biologically active" is not defined by the claim, and give no definition of what this activity is.

Claims 42 and 44 are vague and indefinite because of the recitation of the term "thereof" in subsections (b) and (c). It is not clear to which protein the subsections are referring to. Presumably the subsections are referring to SEQ ID NO: 1, this rejection could be obviated by clarifying the protein to which these subsections refer.

Claims 42 and 44 are vague and indefinite in the recitation of "N- or C- derivatives". It is not clear what this term refers to. There is no guidance provided as to what specific sequences the term " N- or C- derivatives " refers to, and there is no definition provided in the Specification, therefore, the metes and bounds of these claims are unclear.

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***Conclusion***

Claims 1, 10-12, 43 are objected to.

Claims 8, 42, 44 are rejected.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
October 7, 2004



**JOSEPH MURPHY  
PATENT EXAMINER**